

Appl. No. : 10/659,711
Filed : September 11, 2003

REMARKS

Applicant wishes to thank Examiner Stuart Snyder and Supervisor Bruce Campell for the courtesy extended to Nancy Vensko, attorney of record, on 4 August 2006. The Interview Summary Form PTOL-413 summarizes the discussion held at the personal interview. The present response to the outstanding Office Action includes the substance of the Examiner Interview.

A. Disposition of Claims

Claims 20 and 22 to 26 are pending in this application. Claim 23 is withdrawn from consideration as not readable on the elected species. Claim 20 has been amended; support for the amendment is described below. The provisional rejection of Claims 20, 22, and 24 to 26 under 35 USC 101 as claiming the same invention as that of claims in copending Application No. 10/866,193 is appreciated as being withdrawn in view of the abandonment of the latter application. In response to the request that the (presumably non-book) references cited in the Amendment and Response to Office Action dated 13 April 2006 be submitted in an Information Disclosure Statement (IDS), Applicant responds as follows: (1) Lambris, J. D. et al, "Use of synthetic peptides in exploring and modifying complement reactivities" in Activators and Inhibitors of Complement, ed. R. Sim, Kluwer Academic Publishers, Boston, 1993, was already cited in an IDS of record but is re-submitted in an IDS herewith; (2) Genetic Engineering News, Oct. 15, 1993, p.1, is cited in an IDS herewith; (3) Merrill et al., Proc Natl Acad Sci USA 93: 3188 (1996), was already cited in an IDS of record but is re-submitted in an IDS herewith; (4) Vitiello et al., Virus Res 114: 101 (2005), is cited in an IDS herewith; and (5) Isaacs et al., Proc Natl Acad Sci USA 89: 628 (1992), cited in the attached Declaration of Dr. Merrill, was already cited in an IDS of record but is re-submitted in an IDS herewith. As agreed by the Patent Office, there is no patentability-defeating prior art. Reexamination and reconsideration of the application, as amended, are respectfully requested.

B. Compliance with 35 USC 112/1

The Patent Office rejected the claims under 35 USC 112/1 as failing to meet the enablement requirement. Under MPEP 2164, the test for enablement is whether one skilled in the art could make or use the subject matter defined by the claims without undue experimentation. Under MPEP 2164.01(a), the Wands factors are to be considered in

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determining whether any necessary experimentation is undue. Here, the specification is enabling with respect to the claimed subject matter.

i) First, there is considerable direction and guidance in the specification with respect to how to make and use the subject matter defined in the claims. Support for the amendment is located throughout the specification, for example, on page 12, line 1, and following, and page 28, line 20, and following, where a peptide that inhibits complement activation, e.g., the complement antagonizing peptide LARSNL, is contemplated.

ii) Second, there was a high level of skill in the art at the time the application was filed. The level of skill in the molecular biology art was that of a postdoctoral fellow working in the laboratory. *Amgen Inc. v. Hoechst Marion Roussel Inc.*, 57 USPQ2d 1449, 1518 (D. Mass. 2001). Thus, the level of skill in the art was high.

iii) Third, all of the methods needed to practice the invention were well known. As of the 5 April 1994 priority date, for guidance regarding such conditions, see, for example, Sambrook, et al., 1989, *Molecular Cloning, A Laboratory Manual*, Cold Spring Harbor Laboratory Press, New York; and Ausubel et al., 1989, *Current Protocols in Molecular Biology*, Green Publishing Associates, Inc., and Wiley & Sons, Inc., New York.

iv) Per MPEP 2164.01(a), the In re Wands Court held that the specification was enabling with respect to the claims at issue and found that “there was considerable direction and guidance” in the specification; there was “a high level of skill in the art at the time the application was filed;” and “all of the methods needed to practice the invention were well known.” Similarly, here, as indicated above, there was considerable direction and guidance in the specification; there was a high level of skill in the art at the time the application was filed; and all of the methods needed to practice the invention were well known.

v) Declaration of Dr. Merrill. Declaration of Dr. Merrill discusses the issues that would be the most important to address in order to overcome the enablement rejection, i.e., the state of the art at the April 1994 time of filing with regard to predictability of altering the phage surface to diminish complement activation. Considering all the factors related to the enablement issue, it must be concluded that it would *not* require undue experimentation to make and use the subject matter defined in the claims. The conclusion is the claims are in compliance with 35 USC 112/1 as meeting the enablement requirement.

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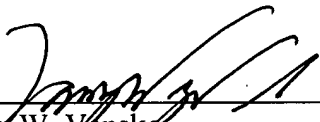
CONCLUSION

In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of all outstanding rejections are respectfully requested. Allowance of the claims at an early date is solicited. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the below-given telephone number.

Respectfully submitted,

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Dated: 8/15/06

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AMEND

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